**HUMAN RIGHTS COMMITTEE**
Children's Hospital of Pittsburgh

**MEMORANDUM**

To: OHRP

From: Human Rights Committee (IRB, Children's Hospital of Pittsburgh)

Re: Draft Interim Guidance: Financial Relationships in Clinical Research: Issues for Institutions, Clinical Investigators, and IRBs to Consider When Dealing with Issues of Financial Interests and Human Subject Protection

Date: 2/20/01

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At its regularly-scheduled, convened meetings on 02/01/01 and 02/15/01, the Human Rights Committee of Children's Hospital of Pittsburgh considered the Draft Interim Guidance Document on Financial Relationships in Clinical Research. The committee voted to forward the following comments:

1. Although it is acknowledged that there have been instances when human subjects have not been protected in the context of a financial conflict of interest, these cases are relatively uncommon. In fact, the most egregious examples of human subject maltreatment (Nazi experiments, Tuskegee) were not motivated by financial considerations.

2. Based on the above considerations, the requirements discussed in the Draft Guidance seem disproportionate to the problem. The assignment of additional monitoring and record-keeping duties to IRBs related to financial conflicts of interest may have the unintended consequence of distracting them from duties more specifically related to the protection of human subjects.

3. Limiting guidance on conflicts of interest to those involving financial matters does not acknowledge the complexity of investigators' motivation. In addition to the pure motive of advancing human knowledge to the end of improving medical care, investigators are also motivated by factors such as prestige and academic rank. This is especially true for investigators in academic settings where there are fixed salaries.

4. For those IRBs that charge a fee for protocol review that is collected prior to review and is not in anyway dependent on the outcome of the review, it is unclear how this constitutes a financial conflict of interest requiring disclosure in consent forms.

5. Institution of the requirements discussed in this Draft Guidance would be more likely to occur in academic institutions with active, local IRBs than in private physicians' offices that do not have Assurances with DHHS. This may have the unintended consequence of shifting clinical research away from academic centers.

6. In the final analysis, the well-being of subjects and the conduct of research depends on the integrity of individual researchers. As researchers are trusted in this regard in every other aspect of research, why is COI singled out as an area in which there cannot be reliance on investigator integrity?

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